



UNITED STATES PATENT AND TRADEMARK OFFICE

clg
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,589	11/25/2003	Stanley B. Prusiner	UCAL-243	7570
24353	7590	09/22/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			ROYDS, LESLIE A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,589	PRUSINER ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-28 are presented for examination.

Applicant's "Response to Restriction/Election Requirement" filed March 14, 2006 in response to the Office Action of February 28, 2006, electing Group I (claims 1-16), drawn to a method of treating a disease resulting from malformed proteins from a mammal comprising administering to said mammal a therapeutically effective amount of a bis-cyclic compound, wherein said bis-cyclic compound is characterized by clearing malformed proteins and by an ability to cross a blood brain barrier of said mammal, is acknowledged.

Upon reconsideration of the claims, the restriction requirement set forth in the Office Action dated February 28, 2006 is herein modified to provide Applicant an opportunity to elect a single species of bis-cyclic compound from those recited in present claims 2-5, 7-8 and 14 and to also provide Applicant an opportunity to elect a single species of disease from those recited in present claim 16.

Requirement for Election of Species

Applicant's election of the invention of Group I (claims 1-16) requires a further election of a single species of bis-cyclic compound and a further election of a single species of disease as defined below.

This application contains claims directed to the following patentably distinct species of (a) bis-cyclic compounds as recited in present claims 2-5, 7-8 and 14 and (b) diseases resulting from malformed proteins as recited in present claim 16.

The species are independent or distinct because:

(a) The species of bis-cyclic compounds recited in the present claims are structurally, functionally, and/or chemically distinct from any one other bis-cyclic compound encompassed by the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other compounds recited in the claims. Notwithstanding that Applicant may have established an underlying common function to this broad genus of compounds, namely, that they are capable of treating the diseases resulting from malformed proteins, it remains that the art does not necessarily recognize such a shared function as being common to each of the variety of distinct compounds encompassed by the claims. Despite the fact that there may be incidental overlap in the art between any one or more of the compounds contained within the claims, such does not change the fact that each of the compounds encompassed by the claims are distinct from one another because they lack a common physical structure or function and, therefore, are considered patentably distinct. In addition, the discovery of any one of the presently claimed compounds for the treatment of the presently claimed diseases would not necessarily anticipate or reasonably suggest or render obvious the use of any one or more of the other compounds claimed for the same objective.

(b) The species of diseases are independent or distinct because each are distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of pharmaceutical agents to be administered, frequency of treatment, etc.) and patient population such that a comprehensive search of the patent and non-patent literature for any one such disorder or condition would not necessarily result in a comprehensive search of any one or more of the other disorders or conditions recited in the present claims.

Art Unit: 1614

Notwithstanding that Applicant may have established an underlying commonality to this genus of disorders or conditions, namely that each is associated with a malformed protein, it remains that the art does not necessarily recognize such a shared characteristic as being common to each of the disparate disorders encompassed by the claim. In addition, while there may be incidental overlap between those patients experiencing, for example, Alzheimer's disease, and those experiencing diabetes, such does not change the fact that each of these disorders or conditions differ from one another in etiology, pathophysiological manifestation, treatment protocol in terms of the dosage amounts and frequency of administration of the therapeutic agent required and patient population affected. For these reasons, they are, therefore, considered patentably distinct. It is noted that the discovery of the treatment of any one of the presently claimed disorders or conditions using a bis-cyclic compound presently claimed would not necessarily anticipate, reasonably suggest or render obvious the treatment of any one or more of the other disorders or conditions of the present claims for the same reasons described above.

Applicant is required under 35 U.S.C. 121 to elect a single bis-cyclic compound from present claims 2-5, 7-8 and 14 and a single disclosed disease associated with a malformed protein from claim 16 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species of bis-cyclic compound and disease that are elected consonant with this requirement and, regarding the compound, identification of each of substituent (i.e., R, etc.) and a structural depiction of the elected bis-cyclic compound. Applicant is required to provide a listing of all claims readable thereon the elected species of bis-cyclic compound and elected species of

Art Unit: 1614

disease, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

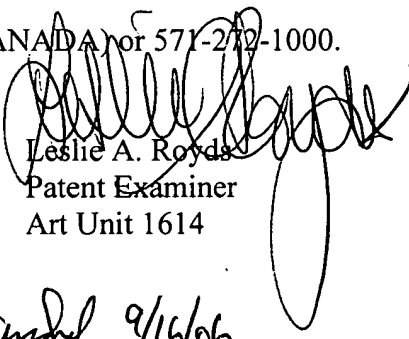
Art Unit: 1614

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie A. Royds
Patent Examiner
Art Unit 1614

August 25, 2006

 9/16/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER